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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|----------------------------|------------------|
| 10/600,004 | 06/18/2003 | Graham Edmund Kelly | 7579.0015-01000 | 6037 |
| 22852 | 7590 | 04/13/2005 | EXAMINER | |
| FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413 | | | DELACROIX MUIRHEI, CYBILLE | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1614 | |

DATE MAILED: 04/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---|-------------------------------------|--|
| Office Action Summary | Application No. 10/600,004 | Applicant(s) KELLY ET AL. | |
| | Examiner Cybille Delacroix-Muirheid | Art Unit 1614 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18,21,28-35 and 41-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18,21,28-35 and 41-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

1. Claims 1-18, 21, 28-35, 41-43, (44) are rejected under 35 U.S.C. 103(a) as being unpatentable over Kelly WO 93/23069 in view of Empie et al., 6,261,565 B1 (both references already of record in parent file) and Kelly 6,340,703.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Concerning new claim 44, this claim is also rejected along with claims 1-18, 21, 28-35, 41-43 for reasons given previously in the office action mailed June 17, 2004. Additional comments regarding claim 44 are presented below.

Response to Amendment(s)

The following is responsive to Applicant's amendment, declarations under 37 CFR 1.132 and terminal disclaimer received Dec. 13, 2004.

Claims 19-20, 22-27, 36-40 are cancelled. New claim 44 is added. Claims 1-18, 21, 28-35, 41-44 are currently pending.

The previous claim objection(s) set forth in paragraph 1 of the office action mailed June 17, 2004 is withdrawn in view of Applicant's amendment and the remarks contained therein.

The previous claim rejections under 35 USC 112, second paragraph, set forth in paragraphs 2-4 of the office action mailed June 17, 2004, are withdrawn in view of Applicant's amendment and the remarks contained therein.

The previous double patenting rejection over claims 6, 9, 14, 15 of USPN 6,340,703 set forth in the office action mailed June 17, 2004 is withdrawn in view of receipt and approval of the terminal disclaimer received Dec. 13, 2004.

However, applicant's arguments traversing the previous claim rejection under 35 USC 103(a) set forth in paragraph 7 of the office action mailed June 17, 2004 have been considered but are not found to be persuasive. Furthermore, applicants' declarations under 37 CFR 1.132 are ineffective to remove the Kelly patent 6,340,703 as prior art.

Regarding the 132 declarations, the MPEP states, "when subject matter, **disclosed but not claimed** in a patent or application publication filed jointly by S and another, is claimed in a later application filed by S, the joint patent or application publication is a valid reference >under 35 U.S.C. 102(a) or (e)< unless overcome by affidavit or declaration under 37 CFR 1.131 or an unequivocal declaration under 37 CFR 1.132 by S that he/she conceived or invented the subject matter disclosed in the patent or application publication and relied on in the rejection. In re DeBaun, 687 F.2d 459, 214 USPQ 933 (CCPA 1982). Please see MPEP 715.01(a) and MPEP 716.10. Therefore, these declarations are ineffective to remove the Kelly patent 6,340,703 as prior art because the subject matter disclosed in the patent is also claimed.

Concerning applicant's arguments pertaining to the substance of the previous claim rejection under 35 USC 103(a), Applicant contends that neither the Kelly publication '069 nor the Empie '565 patent discloses or fairly suggests the claimed inventions. Both references fail to teach high proportions of formononetin. In fact,

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applicant argues that both references teach away from the claimed high proportions of formononetin. Moreover, Kelly '069 is silent with respect to the use of isoflavone compositions for treating bone maladies. Finally, although Empie mentions osteoporosis, it does not indicate whether isoflavones are responsible for the beneficial results against osteoporosis.

Said arguments have been considered but are not found to be persuasive.

The Examiner respectfully maintains that the combination of references renders obvious applicant's claims. Concerning the claimed ratios having a high proportion of formononetin as well as new claim 44, the Kelly patent discloses a method of treating osteoporosis in a patient by administering to the patient a composition containing an effective amount of (10:1 to 1:10) of formononetin and daidzein (please see claims 6, 9, 14, 15). Moreover, the Examiner respectfully maintains since Kelly '069 and '703, in particular, as well as Empie et al. have established that the therapeutic efficacy of the isoflavones is dependent upon their ratio amounts, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the methods and compositions of the prior art such that formononetin and biochanin or genistein or daidzein are present in a ratio that is effective to optimize their therapeutic activity.

The rejection is respectfully maintained.

Conclusion

Claims 1-18, 21, 28-35, 41-44 are rejected.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybill Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

CDM 
April 11, 2005


RAYMOND HENLEY III
PRIMARY EXAMINER
AU 1614